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10/584,383

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04/13/2009

EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,383	Applicant(s) LEE ET AL.	
	Examiner KELAGINAMANE T. HIRIYANNA	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 07/24/2008 in response to office action mailed on 05/28/2008 has been acknowledged.

Claims 1-23 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation "gene carrier.....is a vector or recombinant virus" makes the claim vague and indefinite because gene carrier recombinant virus itself is a vector. Appropriate correction is required.

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation "vector or recombinant virus" makes the claim vague and indefinite because recombinant virus itself is a vector. Appropriate correction is required.

Claims 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.. Claim 6 recites the limitation 'cells' in line 1. There is insufficient antecedent basis for this limitation as such in the claim or in the base claim 1. The base claim 1 has either human cells or animal cells or ex vivo cells. Appropriate corrections are required.

Claims 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation "gene carrier.....is a vector or recombinant virus" makes the claim vague and indefinite because gene carrier recombinant virus itself is a vector. Appropriate correction is required.

Claims 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.. Claim 15 recites the limitation 'cells' in line 1. There is insufficient antecedent basis for this limitation as such in the claim or in the base claim 1. The base claim 1 has either human cells or animal cells or ex vivo cells. Appropriate corrections are required.

Claims 16 (and dependent claim17) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.. Claim 16 recites the limitation 'solid tumor' in line 1. There is insufficient antecedent basis for this limitation as such in the claim or in the base claim 1. . Appropriate corrections are required.

Claims 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation "preventing or treating a solid tumor" makes

the claim vague and indefinite because such is done only to subject or patient with said tumor. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition or agents of human apolipoprotein (a) kringle KIV9-KIV10-KV (LK68) or KV (LK8) and a method of treating solid tumors with AAV or Adenoviral viral vectors as gene carriers and administered to site of solid tumors by direct injection, does not enable prevention of any tumors, does not enable any gene carrier, and any method of administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At issue, under the enablement requirement of 35 U.S.C. 112, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). These factors include, but are not limited to: (1) The breadth of the claims; (2) The nature of the invention; (3) The state of the prior art; (4) The level of one of ordinary skill; (5) The level of predictability in the art; (6) The amount of direction provided by the inventor; (7) The existence of working examples; and (8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below as to show that one of ordinary skill in the art has to go through "undue experimentation" in order to practice the invention.

Nature of the invention: The invention relates to gene therapy and preventing or treating tumors and metastasis by administering any route to a subject the gene therapy

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compositions comprising any gene carrier that expresses recombinant human apolipoprotein (a) kringles KIV9-KIV10-KV (LK68) or KV (LK8). The nature of the invention is such that it required undue experimentation by one of skill in the art to practice the invention in its full scope.

Breadth of the claims And Guidance Provided in the Specification: The scope of the invention encompasses compositions and methods of gene-therapy for preventing or treating any human or animal tumor by administering any “gene carrier” (that for examples encompasses any cells, viruses/viral vectors, plasmid vectors, naked vectors, vectors in liposomes etc.,) by parenteral route a composition that comprises a recombinant nucleic acid that encodes a human apolipoprotein (a) kringle KIV9-KIV10-KV (LK68) or KV (LK8).

The specification only teaches an enabled use of a AAV-viral vector for introducing a recombinant human apolipoprotein (a) kringle KIV9-KIV10-KV (LK68) or KV (LK8) and using a method of administration of direct injection into a solid tumor in mice in mice that apparently results in inhibition of growth of a transplanted tumor and a decrease in the rate of fatality.

The specification does not disclose any enabled examples of composition of “gene carriers” other than said AAV vector, does not disclose any enabled examples of broadly claimed prevention of a tumor, further does not disclose an enabled method of treating any tumor by parenteral administration of said gene-therapy compositions for treating any cancer and further does not teach enabled examples of any chemical method, physical method, or conjugation using liposome or using receptor as a method of administration.

The Application as filed does not enable any prevention of tumors or treatment with the broadly claimed compositions of “gene carriers” and methods of administrations. Since the gene carriers by its broad definitions encompass any recombinant cell therapy in addition to use of viral vectors and non viral vectors and further their broadly claimed parenteral administration, it is incumbent upon the Applicant to provide sufficient guidance or enabled examples.

In the absence of representative number of enabled examples in the specification commensurate with the breadth of the claims one of ordinary skill in the art would

conclude that the invention is unpredictable and would require undue experimentation to practice the invention in its full scope. The test is whether the number of claimed genus/or species of gene carriers and method of delivery and etc., as instantly claimed and prior to the reference date or the date of the activity provided an adequate basis for inferring that the invention has generic applicability.

The level of one of ordinary skill in the Art at the Time of Invention: The level of one of ordinary skill in the art at the time of filing of the instant application is high requiring an advanced degree or training in the relevant field. The status of the art at the time of filing was such that said skilled in the art would not have been able to make or use the invention for its fully claimed scope without undue experimentation.

State of the Art, the Predictability of the Art: At about the effective filing date of the present application art is unpredictable with regard methods in vivo of gene transfers for gene therapeutic purposes both viral and non-viral vectors or compositions of cells or other gene carriers. Further the art is still unpredictable regarding enablement of prevention of any tumors or cancers employing said gene transfers. Even the treatment of tumors using gene therapeutic method art still considers it to be highly experimental area of research and it has been difficult to predict the out come of many therapeutic genes and vector systems because of various factors that govern the expression, therapeutic potential of the transduced genes, and the undesirable host immune reactions etc., in vivo (Reviewed in Goncalves et al, Bioessays, 2005, 27: 506-517; art of record). In addition there exists unpredictability in the art regarding method of parenteral administrations of such gene-therapeutic compositions without specific targeting protocols. More often the compositions in general circulation cause immune reactions and end up in excretory or degradation pathways with the target tissue receiving little or none. Hence, it is incumbent upon the Applicant to provide teachings as to each of the broadly claimed methods work. Only direct injection of the tumors with therapeutic compositions is considered to be reasonably successful. Further the art is unpredictable about the degree to which a foreign gene or vector would interfere with cellular genetic material as observed in treatment of X-SCID patients “ These serious adverse events presented as a leukemia-like syndrome were surprising since the risk of insertional oncogenesis was considered to

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be negligible based on previous trials and on the perceived, though not universally accepted, notion of random retroviral integration" (Goncalves, Bioessays, 2005, 27: 506-517, p. 514, col.2, 1st paragraph). Thus the unpredictability in the art, at the time of instant filing, regarding the methods and consequences of claimed ex vivo and in vivo gene therapies using any "gene carriers" is such that one of ordinary skill in the art finds the claimed invention highly unpredictable and cause undue experimentation to practice the invention in its fully claimed scope.

Amount of experimentation necessary: Because of the lack of working examples, insufficient guidance and direction provided by Applicant, the inherent unpredictability of the art, and the nature of the invention, one of skill in the art would be required to perform a large amount of experimentation to make and/or use the invention in its full scope as claimed by Applicant. Such experimentation would be required to make sufficient number of "gene carriers" including various viral vectors, plasmid constructs and cells expressing appropriate Kringle peptides and deliver them in various modes of parenteral administration in to a subject and assess their efficacy in delivering the gene to target tissue namely tumors. Further one of skill in the art will not able to assess that any prevention of tumor occurred. Still further regarding treatment of a tumor one of ordinary skill has to assess the in vivo effects, both short term and long term, of the different viral vectors or gene carrier cells on the subject health and immunity. Further these claims are not enabled because one of skilled in the art, at the date of filing, would not be able to rely upon the state of the art in order to successfully predict a priori the in vivo effects of claimed gene carriers and efficacy of various delivery routes. Accordingly, in view of the lack of teachings in the art and lack of guidance provided by the specification with regard to an enabled use of sufficient number of gene carriers and delivery methods for preventing or treating a tumor with said compositions as of around the filing date of instant application and for the specific reasons cited above, it would have required undue experimentation for one of skill in the art to make and use the full scope of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 USC 103 (a) as being unpatentable over Chang et al (WO 01/19868 A1; art of record) in view of Trieu et. al (1999, Biochem. Biophys. Res. Comm. 257: 714-718; art of record) and Kikuchi et al., (2002, Blood 100:3950-3959).

The above claims are directed to a pharmaceutical composition containing a gene carrier or cell harboring human apolipoprotein kringle KIV9-KIV10-KV (LK68) or KV (LK8) and in further limitations carrier is a vector or a recombinant virus and the cells harboring vector including hematopoietic stem cells, dendritic cells and to a method of for the prevention or the treatment of a solid tumor including its growth or metastasis by administering said gene carrier.

Regarding claims 1-23 Chang teaches compositions comprising vectors with nucleotide sequences SEQ ID NO: 1 or 2 encoding human apolipoprotein kringle KIV9-KIV10-KV (LK68) or KV (LK8) (Abstract, p.1, lines 8-17, p.4, lines 27-36 bridging p.5). Chang further teaches that proteins encoded by said sequences as anticancer agents and inhibit angiogenesis (Abstract), p.3, lines 10-37 bridging p.4-5) and they inhibit endothelial cell proliferation, migration and suppress lung carcinoma (p.15, lines 10-35 bridging p.16-20). Chang however does not teach "gene carrier" compositions with said nucleic acids encoding human apolipoprotein kringle KIV9-KIV10-KV (LK68) or KV (LK8) and or a method of treating tumors by administering said nucleic acids into any animal.

Regarding claims 1-4, 8-10 and 18-21 Trieu teaches that there is an established link between cancer and Apo(a) (the protein that contains KIV9-KIV10-KV (LK68) or KV (LK8)) levels and a method of treating Lewis lung carcinoma (LL/2) cancer wherein the cancer cells show a delayed growth of tumor and reduced angiogenesis when provided with apo(a) transgene (Abstract and entire article). Regarding claim 6 Trieu teaches providing CHO-K1 cells over expressing truncated human apo(a) transfected using a

vector. Trieu further teaches full length recombinant apo(a) causes tumor suppression (p.714, abstract, col.2, 1st paragraph, 3rd paragraph; p.715, col.1 3rd paragraph, col.2, 1st paragraph; p.716, Fig.2). Trieu additionally teaches that a further characterization of structural components of apo(a) responsible for its previously unappreciated anti-tumor effects may provide the basis for novel and effective cancer treatment methods that employ apo(a) fragment or functional analogs of apo(a) as inhibitors of tumor angiogenesis. Trieu however, teaches that his experiments with a truncated six kringle-IV repeats however, did not show the effect as with a full length Apo(a) coding gene.

However at the time of invention Kikuchi teaches tumor therapy with using kringle-4 containing fragments. Kikuchi teaches gene therapy of tumor using Adenovirus vector containing gene encoding NK4 kringles, short Kringle-4 containing fragments (entire article; abstract)

Regarding limitations in claims 5, 7, 11-15, 22-23 of specific vectors used for methods of delivering and expressing said nucleic acid sequences in animal cells, prior art at the time of invention inherently and clearly teaches the use of several of the claimed vectors including viral vectors (for example see Kuo et al, 2001, PNAS 98:4605-4610; art of record) for delivering therapeutic genes into animal cells and for treating a solid tumor and metastasis thereof.

Thus it would have been obvious to one of skill in the art to try gene therapeutic approach that would parallel the success of polypeptide therapy using LK8 and LK68 apo(a) protein kringle fragments as taught by Chang and further substitute the same for full length apo(a) gene therapeutic vector construct of Trieu or short kringle coding sequences in viral vectors described by Kiuchi or other gene therapy vectors taught by Kuo and prepare and use a composition to treat a solid tumor in an animal subject. One of the skill in the art would have been motivated to use the gene fragment that codes for LK68 and LK8 kringles in specific viral vector/or vector transfected as these gene carriers increase the efficacy of a tumor gene therapy. One of skill in the art would have an expectation of success of making and using a pharmaceutical composition for gene therapy of tumors using gene coding sequences for kringles KIV9-KIV10-KV (LK68) or KV (LK8) cloned in viral or non-viral vectors as the art at the time of invention teaches that the

polypeptide encoded by these sequences efficiently treat tumor and further teaches that full length apo(a) gene therapy or gene therapy using sequences coding for short kringle fragments (NK4) from other kringle domain containing proteins fragments in therapeutic vectors such as Adenovirus vectors are successful and routine. Thus the invention as claimed would have been *prima facie* obvious to one of skill in the art.

Response to Applicant's arguments of 07/24/2008.

The applicant argues Chang et al., did not describe the use of gene carriers or vectors for expression in human or animal cells and Trieu et al does not teach that truncated fragments of apo(a) are effective against tumor angiogenesis and hence a combination of the above two references do not provide an expectation of success and hence the invention is not obvious over the existing prior art.

The Applicants arguments however found not persuasive because in the first place the Applicant should note that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). As far as the motivation to combine the previously cited references and the relevant prior art Applicant should note Chang clearly teaches the tumor therapeutic efficacy of LK68 and LK8 as well as the cDNA sequences coding them where as Trieu clearly teaches the use of DNA sequences comprising said kringles in eukaryotic expression vectors for expressing in animal cells and for gene therapy. Although, Trieu' does not observe success with a fragment of six kringles as he did with the full length apo(a), he does not rule out the possibility of therapeutic potency of such fragments, as indicated by his note "Thus the observed lack of antitumor effects with this truncated apo(a) protein may be due to its inability to effectively interact with blood vessels. Meanwhile prior art (e.g.,

Kikuchi reference) clearly taught that short kringle fragments (NK4) are therapeutic when provided as gene therapeutic composition. Hence, one of skill would have reasonable expectation of success. Thus a combination of the teachings of the above references combined with the relevant prior art teachings (e.g., Kikuchi et al) regarding use of various vectors instant invention would have been obvious to an artisan in the art. Hence the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 8-10, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 11 and 12 of patent NO:6,743,428 B1

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim because the examined claim is either anticipated by, or would have been obvious over, the reference claim.

The subject matter claimed in the instant application is covered by the cited application. The cited claims teach expression vectors (gene carriers) containing nucleic acids coding for KIV9-KIV10-KV (LK68) or KV (LK8). The cited claims of the '3428 broadly claim expression vectors containing nucleic acids coding for KIV9-KIV10-KV (LK68) or KV (LK8). Accordingly, the claimed process in the present application and the cited patent are obvious variants. Therefore, the inventions as claimed are co-extensive.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hirianna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

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